

Docket No.: 64609 (70301)

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit: N/A

In re Patent Application of: Wolfgang Kreisel

Application No.: 10/559,694

Filed: December 6, 2005 Examiner: Not Yet Assigned

For: PROPHYLAXIS AND/OR TREATMENT OF PORTAL HYPERTENSION

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the United States

Patent and Trademark Office is hereby directed to the references listed on the attached

Form PTO/SB/08. It is respectfully requested that the information be expressly considered

during the prosecution of this application, and that the references be made of record
therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed within three months of the U.S. filing date (37 CFR 1.97(b)(1)).

Applicant has not submitted copies of each cited U.S. patent and U.S. patent application as required by 37 CFR 1.98(a)(2)(i), amended October 2004, as the U.S. Patent and Trademark Office has waived this requirement for all U.S. patent applications.

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Applicant submits herewith copies of foreign and non-patents in accordance with 37 CFR 1.98(a)(2).

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 64609 (70301). A duplicate copy of this paper is enclosed.

Dated: March 6, 2006

Respectfully submitted,

John B. Alexander, Ph.D.

Registration No.: 48,399

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PTO/SB/08a/b (07-05)

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Complete if Known Substitute for form 1449A/B/PTO Application Number 10/559,694 INFORMATION DISCLOSURE December 6, 2005 Filing Date STATEMENT BY APPLICANT First Named Inventor Wolfgang Kreisel Art Unit N/A (Use as many sheets as necessary) Not Yet Assigned Examiner Name of 64609 (70301) Sheet 1 Attorney Docket Number

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS						
Examiner	Cite	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines,	
Initials*	No.1	Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	mber ⁴ -Kind Code ⁵ (if known) Date MM-DD-YYYY A	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	
7C.S.	ВА	DE-199 61 302	06-21-2001			
888	BB	WO-94-28902	12-22-1994	Pfizer Limited		
\ /	ВС	WO-02/060449	08-08-2002	Merck Patent GMBH		
V	BD	WO-02/062343	08-15-2002	Merck Patent GMBH	·	
/C.S./	BE	EP-1 097 711	05-09-2001	Pfizer Limited		

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		NON PATENT LITERATURE DOCUMENTS			
Examiner No.1					
	CC	G. Garcia-Tsao, "Portal Hypertension", <u>Current Opinion in Gastroenterology</u> , 2003, pp. 250-258.			
***************************************	CD	R. Wiest, et al., "The Paradox of Nitric Oxide in Cirrhosis and Portal Hypertension: Too Much, Not Enough", Hepatology, Vol. 35, No. 2, 2002, pp. 478-491.			
200000	CE	T. D. Boyer, "Pharmacologic Treatment of Portal Hypertension: Past, Present, and Future", Hepatology, Vol. 34, No. 4, 2001, pp. 834-839.			
000000000000000000000000000000000000000	CF H. C. Herrmann, et al., "Hemodynamic Effects of Sildenafil in Men with Severe Coronary Artery Disease", <u>The New England Journal of Medicine</u> , Vol. 342, No. 22, 2000, pp. 1622 1626.				
00000000	CG	R. M. Zusman, et al., "Overall Cardiovascular Profile of Sildenafil Citrate", <u>The American</u> <u>Journal of Cardiology</u> , Vol. 83(5A), 1999, pp. 35C-44C.			
***	CH	U. Gresser, et al., "Erectile Dysfunction: Comparison of Efficacy and Side Effects of the PDE-5 Inhibitors Sildenafil, Vardenafil and Tadalafil Review of the Literature", European Journal of Medical Research, Vol. 7, 2002, pp. 435-446.			
D. T. Manallack, et al., "The Next Generation of Phosphodiesterase Inhibitors: Structural Clues to Ligand and Substrate Selectivity of Phosphodiesterases", <u>Journal of Medicinal Chemistry</u> , Vol. 48. No. 10, 2005, pp. 3449-3462.					

Examiner Signature	/Christopher Stone/	Date Considered	01/24/2008
533665			

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		NON PATENT LITERATURE DOCUMENTS		
Examiner Cite Initials No.1		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
/C.S./		CJ Y. H. Jeon, et al., "Phosphodiesterase: overview of protein structures, potential therapeutic applications and recent progress in drug development", <u>CMLS Cellular and Molecular Life</u> Sciences, Vol. 62, 2005, pp. 1198-1220.		
20000000000000000	СК	J. D. Corbin, et al., "Molecular Biology and Pharmacology of PDE-5-Inhibitor Therapy for Erectile Dysfunction", <u>Journal of Andrology</u> , Vol. 24, No. 6 Supplement, November/December 2003, pp. S38-S41.		
00000000	CL	J-P. Tasu, et al., "Hepatic Venous Pressure Gradients Measured by Duplex Ultrasound", Clinical Radiology, Vol. 57, 2002, pp. 746-752.		
000000000000000000000000000000000000000	СМ	K. Haag, et al., "Correlation of Duplex Sonography Findings and Portal Pressure in 375 Patients with Portal Hypertension", American Journal of Roentgenol, Vol. 172, 1999, pp. 631-635.		
Potent Inhibitor, 4-((3,4-(Methylenedioxy)benzyl)amino)-6,7,8-trimethoxyquinazoline", J		Y. Takase, et al., "Cyclic GMP Phosphodiesterase Inhibitors. 1. The Discovery of a Novel Potent Inhibitor, 4-((3,4-(Methylenedioxy)benzyl)amino)-6,7,8-trimethoxyquinazoline", <u>Journal of Medicinal Chemistry</u> , Vol. 36, No. 24, 1993, pp. 3765-3770.		
000000000000	СО	Y. Takase, et al., "Cyclic GMP Phosphodiesterase Inhibitors. 2. Requirements of 6-Substitution of Quinazoline Derivatives for Potent and Selective Inhibitory Activity", <u>Journal of Medicinal Chemistry</u> , Vol. 37, No. 13, 1994, pp. 2106-2111.		
***************************************	СР	A. Albillos, et al., "Accuracy of portal and forearm blood flow measurements in the assessment of the portal pressure response to propranolol", <u>Journal of Hepatology</u> , Vol. 27, 1997, pp. 496-504.		
000000000	CQ	S. Chung, "Advances in Endoscopy - Management of bleeding in the cirrhotic patient", Journal of Gastroenterology and Hepatology", Vol. 17, 2002, pp. 355-360.		
000000000	CR	G. McCormack, et al., "A Practical Guide to the Management of Oesophageal Varices", <u>Drugs</u> , Vol. 57, No. 3. 1999, pp. 327-335.		
***************************************	CS	I. Colle, et al., "Sildenafil in Rats with Cirrhosis and Portal Hypertension: Systemic and Splanchnic Haemodynamic Effects", <u>Digest. Dis. Week</u> , 2003, p. A-736.		
000000000	СТ	I. Colle, et al., "Systemic and Splanchnic Hemodynamic Effects of Sildenafil in Rats with Cirrhosis and Portal Hypertension", Hepatology, Vol. 36, No. 4, 2002, p. 510A.		
***************************************	CU	N. Garcia, Jr., et al., "Systemic and Portal Hemodynamic Effects of Sildenafil Citrate", Gastroenterology, Vol. 120, No. 5, p. A378.		
V	CV	H. A. Ghofrani, et al., "Sildenafil zur Therapie der schweren pulmonalen Hypertonie und des beginnenden Rechtsherzversagens", Pneumologie, Vol. 56, 2002, pp. 665-672.		
/C.S.	cw	D. A. Langer, et al., "Nitric oxide and portal hypertension: Interface of vasoreactivity and angiogenesis", Journal of Hepatology, Vol. 44, 2006, pp. 209-216.		

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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